

**REMARKS**

This is in response to the 08 February 2010 office action.

The meeting with examiner Christine Nelson and supervisory primary examiner Thomas Barrett on 27 May 2010 is acknowledged with appreciation. At the meeting the independent claims were discussed and the prior art of record was discussed. No agreement was reached however the examiners appeared to agree that the combination of a bone implant and a barrier material (e.g., claim 40) has attributes that may avoid the prior art. The examiners wished to further consider this point.

Withdrawn claims 1-22 remain canceled without prejudice or disclaimer of the subject matter therein. Claims 35 and 37 also remain withdrawn without prejudice or disclaimer of the subject matter therein. Applicant reserves the right to file a continuing application including the subject matter of the canceled claims and the withdrawn claims.

**The 35 U.S.C. 102(b) rejection over Watanabe.**

Claim 23 stands rejected under 35 U.S.C. 102(b) as anticipated by Watanabe (U.S. Patent No. 5,265,278).

Claim 23 is directed to a bone instrumentation cover comprising a hollow cap sized for encapsulating a part of a bone instrumentation which has been installed in a bone, adapted for placement in the body of the animal, for encapsulating a part of the bone instrumentation, for providing a medically safe physical barrier and for separating the part of the bone instrumentation from substantially all of the surrounding soft tissue so that the hollow cap prevents ingrowth of substantially all of the surrounding soft tissue through the cap into the bone instrumentation which projects from the bone.

Watanabe is directed to a

hair cap 1 comprises an inner cap 2 made of a synthetic resin material, e.g. vinyl. A ceramic paper cap 3 of a hair cap shape made of a far infrared ceramic paper material, which exhibits a resistance to heat up to 80<sup>0</sup> C and is coated with a polyethylene coating, is arranged to cover over the outer surface of the inner cap 2. An outer cap 4 made of a synthetic resin, e.g. impermeable polyethylene or vinyl, is arranged to cover over the outer surface of the ceramic paper cap. A rubber string 5 having an annular shape is enclosed in the opening hem of the outer cap 4 as it is sewed down

or bonded to the opening end of the same. (Column 1, line 61 to column 2, line 6).

The outer cap 4 is coated on its inner side with a silver metallic layer containing a powder of alumina for reflection of the far infrared rays emitted from the ceramic paper cap. (Column 2, lines 21-24).

To support a rejection of a claim under 35 U.S.C. 102(b), it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference.<sup>1</sup>

Watanabe's hair cap is comprised of layers of material including synthetic resin, a far infrared ceramic paper, silver metallic material containing powder of alumina, a polyethylene and rubber. The disclosure in Watanabe does not relate any steps for making the hair cap that would ensure the cap is sterile and safe for use in the body of an animal. It is submitted that one of ordinary skill in the art would not use the materials in Watanabe's hair cap in the body of an animal at least because they are not disclosed as medically safe materials. Claim 23 requires a hollow cap being adapted for placement in the body of an animal and adapted to provide a medically safe physical barrier between the part of the bone instrumentation and the surrounding bone and soft tissue. Watanabe's hair cap is made of materials not adapted for placement in the body of an animal. Watanabe's hair cap is made of materials that are not medically safe in that they are not adapted to provide a medically safe physical barrier in the body of an animal. Thus, Watanabe does not anticipate claim 23.

Claim 23 requires a hollow cap being sized for encapsulating installed bone instrumentation. Watanabe's hair cap is sized to cover the head and hair of a person (see Fig. Nos. 1 and 6) and is not adapted to be shaped to cover installed bone instrumentation. Bone implants are elements in a variety of shaped and Watanabe's hair cap is sized to fit a person's head. There is no disclosure in Watanabe of the hair cap being sized to cover installed bone instrumentation. Accordingly, Watanabe's hair cap is not adapted to provide this feature of claim 23.

At the meeting the examiners urged that Watanabe's hair cap is capable of the hollow cap limitations of claim 23. Although a prior art device "may be capable of being modified to run

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<sup>1</sup> See *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984).

the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so.”<sup>2</sup> There is no teaching or suggestion in Watanabe to use the hair cap as a bone instrumentation cover as recited in claim 23. One does not use materials in the body of an animal that have not been accepted as medically safe for use in the body of an animal. Watanabe’s hair cap is not a medically approved mater for use in the body of an animal as recited in claim 23.

Applicant has discovered a problem and solution that is not disclosed or suggested in the prior art of record (including Watanabe). The problem is the ingrowth of bone or soft tissue into bone instrumentation installed in the body of an animal. The solution is a medically safe cover over the protruding portions of the bone instrumentation. Watanabe is not directed to the subject matter as a whole of applicant’s invention and Watanabe does not disclose a medically safe cover capable of being installed to cover protruding portions of bone instrumentation installed in bone of an animal.

For at least these reasons applicant requests reconsideration and withdrawal of this ground of rejection.

**The 35 U.S.C. 102(b) rejection over Ellman.**

Claims 23, 29-31, 36 and 38-39 stand rejected under 35 U.S.C. 102(b) as anticipated by Ellman (U.S. Patent No. 4,428,375).

Ellman discloses a bag 15 to compress an organ to assist in healing a fracture in the organ. Ellman discloses “bag 15 has a mesh or network construction” (column 2, line 32). The mesh has openings 19. Ellman states that “another advantage is that the multiple interstices or openings in the net allows ingrowth of tissue through the net openings and around the net solid parts and thus enhances healing.” (Column 3, lines 55-58.)

Applicant’s claims recite that the cover or shield separates the bone implant from substantially all of the surrounding soft tissue. Ellman’s bag 15 does not and cannot separate the implant from the soft tissue because the bag 15 has holes in the bag 15 (i.e., a mesh has holes or openings which as disclosed in Ellman permit ingrowth). A declaration under 37 CFR 1.132 by Jeffery Thramann (Chairman of the board of Lanx, Inc., a licensee of subject matter in the

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<sup>2</sup> In re Mills, 916 F.2d 680, 682, 16 USPQ2d at 1432. See also In re Fritsch, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992).

present application) was filed on 11 December 2009 and states that “Ellman’s device would not ‘provide a medically safe physical barrier between the part of the bone instrumentation and the surrounding bone and soft tissue...’ nor would it ‘prevent ingrowth of substantially all of the surrounding soft tissue through the cap into the bone instrumentation’....” The declaration by Jeffery Thramann provides evidence that Ellman does not teach or suggest the claimed subject matter. Accordingly Ellman does not anticipate the claimed invention and Ellman actually teaches away from the claimed invention in that Ellman discloses the desirability of ingrowth (as quoted above) whereas applicant’s claimed invention prevents ingrowth. One following the teaching of Ellman would be discouraged from following the path set out by applicant and would be led in a direction away from the invention provided by the applicant.

At page 4 of the office action it is urged that

with regard the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Ellman which is capable of being used as claimed if one so desires to do so, In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

Assertion that that the present claims do not impose any structural limitations on the claims distinguishable over Ellman is incorrect. The functional language in these claims is required to be “evaluated and considered just like any other limitation of the claim...” (MPEP, Section 2173.05(g)). Thus, the present functional claim language is a limitation that must be evaluated with the other claimed limitations. Furthermore, Ellman is not capable of being used to perform the claimed functions as discussed in the above noted Thramann declaration. This declaration is evidence that Ellman is not capable of the claimed functions. Accordingly, the functional language of the claims may not be disregarded. The assertion that functional language of claims may be disregarded because it simply describes inherent functions of claimed structural elements, violates "all elements" rule of claim construction.<sup>3</sup>

The governing law is stated in Ethyl Molded Products Co. v. Betts Package Inc. 9 USPQ2d 1001, 1030 (DC EKy 1988).

It is well settled that there is nothing intrinsically wrong in defining something by what it does rather than by what it is. Product claims may be drafted to include process steps to wholly

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<sup>3</sup> Hollister Inc. v. E.R. Squibb & Sons Inc. U.S. Court of Appeals Federal Circuit CA FC 14 USPQ2d 2069 4/30/1990 Decided April 30, 1990.

or partially define the claimed product. To the extent that the process limitations distinguish the products over the prior art, they must be given the same consideration as traditional product characteristics.<sup>4</sup>

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.<sup>5</sup> To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The assertion at page 4 of the office action that Ellman is capable of being used as claimed if one so desires to do so is simply incorrect as evidenced by the Thramann declaration.

Claim 23 is directed to a bone instrumentation cover comprising a hollow cap adapted for placement in the body of the animal, for encapsulating a part of the bone instrumentation, for providing a medically safe physical barrier and for separating the bone instrumentation from substantially all of the surrounding soft tissue so that the hollow cap prevents ingrowth of substantially all of the surrounding soft tissue through the cap into the bone instrumentation which projects from the bone. Claim 30 similarly is directed to a bone instrumentation cover comprising a hollow cap shaped to encapsulate a part of a pedicle screw which has been installed in bone in the body of a human, the hollow cap being shaped to encapsulate a part of the pedicle screw which projects from the bone and is in the body of the human, the hollow cap being adapted for placement in the body of the human to separate the part of the pedicle screw in the body of the human from substantially all of the surrounding soft tissue so that the hollow cap prevents ingrowth of bone or tissue through the cap into the bone instrumentation which projects from the bone. Claim 36 is directed to a bone instrumentation cover comprising a cap comprising means adapted for placement in the body of the animal and for separating a projecting portion of bone instrumentation which has been installed in bone in vivo in the animal from substantially all of the surrounding soft tissue and for providing a medically safe physical barrier between the part of the bone instrumentation which projects from the bone and the

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<sup>4</sup> In re Hallman, 655 F.2d 212, 215 [ 210 USPQ 609, 611] (CCPA 1981).

<sup>5</sup> In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

surrounding soft tissue in the animal so that the cap prevents ingrowth of substantially all of the surrounding soft tissue into the bone instrumentation which projects from the bone.

Ellman discloses a bag 15 to compress an organ to assist in healing a fracture in the organ. Ellman discloses “bag 15 has a mesh or network construction” (column 2, line 32). The mesh has openings 19. Ellman states that “another advantage is that the multiple interstices or openings in the net allows ingrowth of tissue through the net openings and around the net solid parts and thus enhances healing.” (Column 3, lines 55-58.)

In applicant’s claims 23, 30 and 36 the cover or shield is adapted for separating the bone implant from substantially all of the surrounding soft tissue so as to prevent ingrowth. Ellman’s bag 15 does not and cannot separate the implant from the soft tissue because the bag 15 has holes in the bag 15 (i.e., a mesh has holes or openings which as disclosed in Ellman permit ingrowth). Accordingly Ellman does not anticipate the claimed invention and Ellman actually teaches away from the claimed invention in that Ellman discloses the desirability of ingrowth (as quoted above) whereas applicant’s claimed invention prevents ingrowth. One following the teaching of Ellman would be discouraged from following the path set out by applicant and would be led in a direction away from the invention provided by the applicant.

Ellman discloses that the mesh or network of the bag 15 has holes 19 which are “3-9 mm in size” (column 2, lines 46-52). Even a layman would know that Ellman’s bag 15 with holes that size does not and can not prevent “ingrowth of substantially all of the surrounding soft tissue through the cap into the bone instrumentation which projects from the bone” as recited in claim 23, is not “adapted to separate the part of the pedicle screw in the body of the human from surrounding bone and soft tissue...” as recited in claim 30 and is not a means “for separating a projecting portion of bone instrumentation which has been installed in bone in vivo in the animal from substantially all of the surrounding soft tissue and for providing a medically safe physical barrier between the part of the bone instrumentation which projects from the bone and the surrounding soft tissue in the animal so that the cap prevents ingrowth of substantially all of the surrounding soft tissue into the bone instrumentation which projects from the bone” as recited in claim 36.

Claim 30 is amended to recite the hollow cap being adapted for permanent placement in the body of the human. Support for this limitation is found at, for example, paragraph 0017 of applicant’s published application (U.S. Publication No. 2005/0049596). This limitation serves to

further clarify that Ellman's disclosure that the net allows ingrowth of tissue through the net openings does not anticipate claim 30 wherein ingrowth is being prevented.

Claim 36 is amended to clarify that the "means for" clause is a 35 U.S.C. 112, sixth paragraph limitation.

For at least the above-noted reasons, Ellman does not anticipate the invention of independent claims 23, 30 and 36 (and dependent claims 24-29, 31-34, 38 and 39).

**The 35 U.S.C. 102(b) rejection over Barron et al.**

Claims 40-43 are rejected as anticipated by Barron et al. (U.S. Patent Publication No. 2003//0163161).

Claim 40 is directed to the combination of a bone implant and a barrier comprising a bone implant capable of extending from the bone of an animal and a barrier material adapted for snugly covering only the portion of the bone implant in the animal which projects from the bone and separating the bone implant from substantially all of the surrounding soft tissue, wherein the barrier material is a medically safe physical barrier between the portion of the part of the bone implant that is covered and the surrounding soft tissue of the animal and wherein the barrier material prevents ingrowth of substantially all of the surrounding tissue into the instrumentation.

A declaration under 37 CFR 1.132 by Jeffery Thramann (Chairman of the board of Lanx, Inc., a licensee of subject matter in the present application) was filed on 21 May 2010 and states that

Barron further discloses that it is undesirable for a non-resorbable cover to 'remain, in part or in whole, in the body'. [0006] Rather Barron discloses that the cover should be made of a material that 'erodes or is dissolved within the patient after a period of time. Thus, following implantation of the bone anchor, the protective cover material is absorbed by natural biological processes.' [0012] 'The bioabsorbable material dissolves with 90....]Preferably] within 30 days.' These statements by Barron emphasize that his cover is a pre-placement protective cover that is not needed after implantation and therefore does not persist.

The declaration by Jeffery Thramann provides evidence that Barron does not teach or suggest the claimed subject matter.

Claim 40 requires a barrier material adapted for snugly covering only the portion of the bone implant in the animal which projects from the bone and separating the bone implant from

substantially all of the surrounding soft tissue. The Barron device does not persist and thus is not adapted for separating the bone implant from substantially all of the surrounding soft tissue. Barron is designed to dissolve within days and thus would not provide the claimed barrier material that prevents ingrowth as recited in claim 40.

Claim 40 is amended to clarify that the barrier material is adapted to be installed on the bone implant after the implant has been installed in the bone of an animal. Support for this limitation is found at, for example, paragraph 0018 of applicant's published application (U.S. Publication No. 2005/0049596) wherein the cover is stated to be installed after placement of the bone instrumentation. This limitation clarifies that the barrier material is installed after the bone implant is installed. Barron does not disclose this feature.

For at least these reasons applicant requests reconsideration and withdrawal of this ground of rejection.

**The 35 U.S.C. 103(a) rejection over Ellman and Barron et al.**

Claims 40-45 are rejected as obvious over Ellman in view of Barron et al.

The office action urges "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Ellman having at least a hollow cap comprising a hydrogel in view of Barron so that the barrier can better protect the instrumentation by being biocompatible as well as absorbing body fluid in the surgical area." (Office action, pages 5-6.)

Barron is not cited for and does not make up for the deficiencies in Ellman. As discussed above with respect to the rejection of claims 23, 29-31, 36 and 38-39, Ellman's bag 15 with holes does not and can not prevent "ingrowth of substantially all of the surrounding tissue into the instrumentation" as recited in claim 40. The use of Barron's hydrogel as the bag material of Ellman would not prevent ingrowth.

For at least these reasons applicant requests reconsideration and withdrawal of this ground of rejection.

**Conclusion.**

For all of the above reasons claims 23-34, 36 and 38-45 appear to be in condition for allowance and such is respectfully requested.

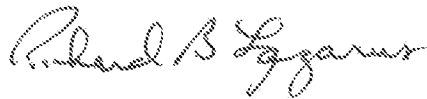


If there is any issue remaining to be resolved, the examiner is invited to telephone the undersigned so that resolution can be promptly effected.

It is requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response with the fee for such extensions and shortages in other fees, being charged, or any overpayment in fees being credited, to the Account of Barnes & Thornburg, Deposit Account No. 02-1010 (6714-46501).

Respectfully submitted,

BARNES & THORNBURG LLP

A handwritten signature in cursive script, appearing to read "Richard B. Lazarus".

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